DEPARTMENT OF HEALTH & HUMAN SERVICES M975N Public Health Service

BUFFALO DISTRICT
Food and Drug Administration
599 Delaware Avenue
Buffalo, NY 14202

5 June 1997

WARNING LETTER BUF 97-20

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Richard Carmen, CEO
Gateway Trade Center, Inc.
2544 Clinton Street
Buffalo, New York 14224

Dear Mr. Carmen:

An inspection of your vessel watering point at Gateway Trade Center, 1951 Hamburg Turnpike, Lackawanna, NY, was performed on 12 and 16 May 1997, by Erie County Department of Health Investigator Mark Kowalski. This inspection was made under the authority of the Public Health Service Act and the Federal Food, Drug and Cosmetic Act. The list of inspectional observations (FDA-483) and the inspection summary - Vessel Watering Point Sanitation Reports (FDA-2521), were issued to, and discussed with, Fred Finger, Port Director, and Neil Long, Project Manager, at the conclusion of the inspection. Copies of those reports are enclosed for your reference.

The inspection revealed significant deviations from the Interstate Conveyance Sanitation Regulation, Part 1250, promulgated under authority of the Public Health Service Act and Federal Food, Drug and Cosmetic Act. Deviations include failure to provide adequate back flow prevention; failure to insure periodic testing of backflow devices by a certified tester; failure to locate hydrant boxes and back flow prevention devices in flood free areas; and, failure to provide outlet cap and keeper chain.

As a result of these inspectional findings, this facility has been classified as "non-approved." A "non-approved" classification means you cannot provide potable water to interstate conveyances from this location.

The above listed violations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the regulations. You should take prompt action to correct these and all violations existing at your firm. Failure to take such action may result in regulatory action, such as injunction, without further notice.

Please notify this office, within 15 days, of the specific steps you have taken, or intend to take, to correct these violations. Your response may be directed to Raymond D. Kent, Team Leader, at the above address.

Sincerely,

Robert L. Hart
Acting District Director

Encs:

Copy of FDA-483
Copy of FDA-2521(2)

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Letter sent by Fax on 6/5/97